

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:  
JAMES B. MYERS, JR.  
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY  
LLP  
BANK ONE CENTER/TOWER, SUITE 3700  
111 MONUMENT CIRCLE  
INDIANAPOLIS, IN 46204

Date of mailing  
(day/month/year) **11 JAN 2005**

Applicant's or agent's file reference <b>48003-4SEMAF</b>		<b>FOR FURTHER ACTION</b> See paragraph 2 below	
International application No. <b>PCT/US04/32289</b>	International filing date (day/month/year) <b>30 September 2004 (30.09.2004)</b>	Priority date (day/month/year) <b>30 September 2003 (30.09.2003)</b>	
International Patent Classification (IPC) or both national classification and IPC <b>IPC(7): A61K 51/00 and US Cl.: 424/1.53, 1.11, 9.1, 1.65</b>			
Applicant <b>SEMAFORE PHARMACEUTICALS, INC.</b>			

1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input checked="" type="checkbox"/> | Box No. II   | Priority   |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application  |

**ENTERED**  
 11 JAN 2005

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized Officer Cybille Delaetola-Muirheid Telephone No. 571-272-0572
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/32289

**Box No. I Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. II Priority

1. ☐ The following document has not yet been furnished:

☐ copy of the earlier application whose priority has been claimed (Rules 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rules 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority has been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application  
☒ claims Nos. 4-6,10,14-16,20 and 21

because:

- ☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4-6,10,14-16,20 and 21 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 4-6, 10, 14-16, 20-21 are improper multiple dependent claims and are not drafted pursuant to Rule 6.4(a).

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- |                            |                          |                                   |
|----------------------------|--------------------------|-----------------------------------|
| the written form           | <input type="checkbox"/> | has not been furnished            |
|                            | <input type="checkbox"/> | does not comply with the standard |
| the computer readable form | <input type="checkbox"/> | has not been furnished            |
|                            | <input type="checkbox"/> | does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-3, 7-9, 11, 12-13, 17-19, 22-27</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>1-3, 7-9, 11, 12-13, 17-19, 22-27</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-3, 7-9, 11, 12-13, 17-19, 22-27</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 7-9, 11, 12-13, 17-19, 22-27 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed compositions or methods of inhibiting tumor growth by administering the claimed compositions. Furthermore, the claimed subject matter can be made or used in industry.